REMARKS

Reconsideration of this application is respectfully requested. Applicants note that the objection to the specification, the rejection of claims 1, 4, 7 and 10 under 35 U.S.C. 102(a), 102(b) and 102(e), and the rejection of claims 1, 4, 7 and 10 under 35 U.S.C. 112, second paragraph, have been withdrawn. Claims 1 through 10 remain rejected under 35 USC §§ 101, 112 (first and second paragraphs), and 102(b). New claims 24 through 26 have been added; support for the claims is found in the specification, at page 9, lines 3 through 6. New claims 27 though 29 have also been added; support is found in the specification, for example at page 3, lines 15 through 17.

Rejections under 35 U.S.C. § § 101 and 112

Claims 1-10 remain rejected under 35 U.S.C. § 101 for allegedly lacking utility, for reasons of record in the previous Office Action. The claims also remain rejected under 35 U.S.C. § 112 as not being enabled for allegedly lacking utility. Applicants traverse the rejection.

The claims in the present application are directed to polynucleotides, which have specific, substantial and credible utility on their own, as previously stated by Applicants, in analyzing abnormalities associated with gene mapping to chromosome 2, to distinguish conditions in which this marker is rearranged or deleted, and the encoded polypeptides have use in protein purification, identification or isolation of cells to which the polypeptides bind, as carriers and research tools, and in the development of antibodies that distinguish between IL-1 family members, for the reasons discussed in Amendment A and incorporated by reference herein.

In contrast to the Examiner's assertion that Applicants have not disclosed a utility associated with the mapping of the instant polynucleotides to chromosome 2q11-12, Applicants specifically asserted in their specification that the claimed polynucleotides are useful in analyzing abnormalities associated with this region, to distinguish conditions in which this marker is rearranged or deleted (present specification, page 27, lines 22 through 25, and USSN 60/135,758 pages 37, lines 6 through 9). The Exhibits provided with Applicants' previous response demonstrated that there are conditions known in the art in which the 2q11-12 region is rearranged

or deleted; Applicants respectfully reiterate that the claimed polynucleotides can be used to detect the rearrangement or deletions described in the Exhibits.

The claimed polynucleotides also have utility in expression of polypeptides, as stated in the present application, for example at page 4, lines 30 through 33 (and in the earliest priority document). As noted in the present application (and in the priority applications), IL-1 eta polypeptides, being members of the IL-1 family, have numerous utilities in modulating an inflammatory response. In particular, Applicants disclose that IL-1 eta polypeptides may be used in a screening assay for compounds and small molecules which inhibit activation by (antagonize) IL-1 eta polypeptide (present specification, page 20, line 36 through page 21, line 4; also disclosed in USSN 60/135,758, at page 34, lines 18 through 25).

As further proof of the utility of IL-1 eta polypeptides, Applicants submit herewith a Declaration of John Sims under 37 CFR § 1.132, demonstrating that IL-1 eta is a proinflammatory cytokine, and therefore is useful in a screening assay as stated in the present application (and in the priority application). As noted by Dr. Sims in paragraph 2 of his Declaration, a new nomenclature has been implemented for the IL-1 family, under which IL-1 eta is referred to as IL-1F8 (i.e., the eighth member of the IL-1 family). Dr. Sims affirms that IL-1 eta and IL-1F8 are the same protein.

He then goes on to state that he prepared or directed the preparation of an expression vector used to express IL-1 F8 as a glutathione S-transferase (GST) fusion protein which was purified and used in several experiments to analyze its activity (Declaration of John Sims, paragraph 3). One such experiment is described in paragraph 4 of Dr. Sims' Declaration. As stated in paragraph 5 of his Declaration, the results of this experiment results indicated that IL-1F8 induced the production of certain cytokines, confirming its activity as a proinflammatory cytokine.

In other experiments, IL-1F8 was shown to activate NFkappaB and MAPKs (JNK and ERK1/2) in NCI/ADR-RES cells (Declaration of John Sims, paragraph 6). Dr. Sims states, in paragraph 7, that induction of proinflammatory cytokines and activation of NFkappaB and MAPKs are activities that IL-1F8 shares with other proinflammatory members of the IL-1 family,

and concludes that IL-1F8 is capable of activating responses that enhance immune responses and promote inflammation, and thus plays a role in the immune system and in the pathogenesis of inflammatory diseases.

In paragraph 8, Dr. Sims states that proinflammatory members of the IL-1 family have served as targets in testing and identifying antagonists thereof for use in treating inflammatory conditions. He concludes that the fact that IL-1F8 shares the ability to induce production of proinflammatory cytokines and activate NFkappaB and MAPKs with other proinflammatory members of the IL-1 family confirms that IL-1F8 polypeptides will be useful in a screening assay for compounds and small molecules which inhibit activation by (antagonize) IL-1F8 polypeptide, as disclosed in the above referenced patent application.

Accordingly, in addition to the uses discussed in Applicants previous response, which were asserted in the present and priority applications, the polypeptides encoded by the claimed nucleic acids also have utility in screening assays for compounds and small molecules which inhibit activation by (antagonize) IL-1F8 polypeptides. This utility is asserted in the presented specification, and was asserted in the earliest priority application. It is a specific utility (i.e., it is not one shared by every polypeptide encoded by a nucleic acid), and it is substantial in that it provides real-world benefit to the public (i.e., it is a public benefit to provide polypeptides useful in screening for compounds and small molecules which inhibit activation by (antagonize) IL-1F8 polypeptides). Accordingly, Applicants respectfully submit that they have asserted at least one utility that is specific, substantial and credible, and that the claimed invention possesses utility and is enabled. Thus, Applicants respectfully request that the rejection under 35 USC § 101 and the corresponding rejection under 35 U.S.C. § 112 be withdrawn.

Rejections under 35 U.S.C. § 112

Claims 1, 4, 7 and 10 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled. The Examiner asserts that since there is no functional description, it is unpredictable as to which variants, if any, have the same function. Applicants submit that absolute

predictability is not required for enablement, if it is a matter of routine experimentation to make such variants and evaluate them, which is true in the present case. However, Applicants have amended the claims, without prejudice, in order to place them in better form for allowance or appeal. Applicants specifically reserve the right to pursue claims to variants, as in a continuing application. Accordingly, Applicants request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claims 1, 4, 7 and 10 remain rejected under 35 U.S.C. § 112, second paragraph, as allegedly lacking sufficient written description, for reasons of record in the previous Office Action. Applicants respectfully disagree, and submit that the claims and specification clearly and succinctly described Applicants' inventive polynucleotides. However, Applicants have amended the claims, without prejudice, in order to place them in better form for allowance or appeal. Applicants specifically reserve the right to pursue claims to variants, as in a continuing application. Accordingly, Applicants request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejection under 35 U.S.C. § 102(b)

Claims 1 through 10 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Smith et al. According to the Examiner, Applicants are not entitled to priority to USSN 60/135,758, and the presently claimed polynucleotides are accordingly allegedly anticipated by Smith et al. Applicants respectfully disagree; as discussed in the previous response and herein, the present specification and the earliest provisional application to which it claims priority discloses at least one specific, substantial and credible utility for the claimed polynucleotides.

Applicants specifically asserted in their specification that the claimed polynucleotides are useful in analyzing abnormalities associated with this region, to distinguish conditions in which this marker is rearranged or deleted. This utility was asserted in the present specification, at page 27, lines 22 through 25, and in the earliest priority document, USSN 60/135,758, at pages 37, lines

6 through 9. Furthermore, Applicants disclose that IL-1 eta polypeptides (which are encoded by the presently claimed polynucleotides) may be used in a screening assay for compounds and small molecules which inhibit activation by (antagonize) IL-1 eta polypeptide in the present application and the priority document (present specification, page 20, line 36 through page 21, line 4; USSN 60/135,758, at page 34, lines 18 through 25).

Accordingly, Applicants are entitled to priority from the earliest filed provisional application in this family. Smith et al., being published after the priority date, is not available as prior art under 35 U.S.C. § 102(b) or any other section of 35 U.S.C. § 102, and Applicants respectfully request that the rejection be withdrawn.

Applicants also respectfully submit that the priority document, at the very least, demonstrates that they were in possession of that which was disclosed by Smith et al. and reserve the right to antedate the teachings of Smith et al. as by a Declaration under 37 CFR § 131 or other appropriate means.

CONCLUSIONS

Claims 1 through 10 and 24 through 29 are now pending in the application and are believed to be in condition for allowance. If the examiner has any questions or concerns about the present claims, she is asked to contact the undersigned at the direct dial number given below, to facilitate prosecution and speed allowance of the claims.

Respectfully submitted,

Patricia Anne Perkins
Registration No. 34,693
DIRECT DIAL (206)265-4782

Immunex Corporation/PAP
Law Department
51 University Street
Seattle, WA 98101
(206) 587-0430